

December 4, 2001, it was determined that no formal drawings need to be specially sent when an application enters the U.S. phase under § 371 when the PCT application is included with the filing and the drawings are published in the PCT application. Accordingly, applicants respectfully submit this response to the Office Action of October 24, 2001, and ask that the following amendments be entered.

AMENDMENTS

In the Claims

Please amend claims 24, 36, 37, 40, 44 and 45 as follows.

24. (once amended) A process for the isolation and purification of HMG-CoA reductase inhibitors from mycelium biomass which comprises:

clarifying a mycelium broth and concentrating the clarified broth to a lower volume,

acidifying of the concentrate to a pH value in the range of 4.5 to 7.5, followed by extracting the HMG-CoA reductase inhibitor with ethyl acetate;

optionally performing lactonization;

crystallizing the HMG-CoA reductase inhibitor from:

i) a water miscible organic solvent; and

ii) an organic solvent,

wherein before crystallizing, the inhibitor is dissolved in said organic solvents at a temperature of between about 10 to 40°C.

Sub E3
B2

36. (once amended) The process according to claim 24, wherein the crystallization step from an organic solvent comprises dissolving the HMG-CoA reductase inhibitor in said organic solvent at a concentration of 10 to 35 g/L, and removing one-third to three-fourth of said organic solvent.

E

37. (once amended) The process according to claim 24, wherein the organic solvent used in the crystallization step is ethyl acetate.

Sub E4
B3

40. (once amended) A process for the purification of HMG-CoA reductase inhibitors which comprises subjecting the HMG-CoA reductase inhibitor to combined crystallization steps, which comprise crystallization from a water-miscible organic solvent and crystallization from an organic solvent, wherein the (limited) solubility is in the range of about 0.25 g/100 mL and about 30 g/100 mL, as final steps to obtain HMG-CoA reductase inhibitors having a purity higher than 99.6%.

E

Sub E6
B4

44. (once amended) The process according to claim 40, wherein said crystallization from an organic solvent comprises dissolving the HMG-CoA reductase inhibitor in said organic solvent at a concentration of 10 to 35 g/L, and removing one-third to three-fourth of said organic solvent.

E

45. (once amended) The process according to claim 40, wherein ethyl acetate is used as the organic solvent.